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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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# Application No. Applicant(s) 10/573.041 PELTONEN ET AL. Office Action Summary Examiner Art Unit HENG M. CHAN 1793 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 21 September 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-30 is/are pending in the application. 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-21 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date \_

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Art Unit: 1793

#### DETAILED ACTION

## Election/Restrictions

Applicant's election with traverse of claims 1-21 in the reply filed on 9/21/2009 is acknowledged. The traversal is on the ground(s) that (1) there are overlapping technical features between the four groups of claims (e.g., claim 24 depends on claim 1) and (2) there would be no undue burden on the Examiner to examine the four groups of claims.

This is not found persuasive because the claims were divided into four groups based on the fact that they do not relate to a single generally inventive concept under PCT Rule 13.1 for reasons stated in the previous Office action, not based on the dependency of individual claims. For the same reason, there would be undue burden on the Examiner to examine the four groups of claims.

The requirement is still deemed proper and is therefore made FINAL. Claims 22-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 9/21/2009

### Claim Objections

 Claims 1, 4, 5, 11, 13-15, 18, 20, and 21 are objected to because of the following informalities: Claim 1: "a" should be inserted before "starch derivative" in line 3; "the" should be inserted before "starch derivative" after "dissolving" in line 3, after "which" in line 5, and after "of" in line 7; "solution" should be changed to "solvent" in line 4; "the" should be inserted before "solvent" in line 8; a comma should be inserted after "dissolve" in line 6.

- Claim 4: "a" should be changed to "the" before "solution" in line 2.
- Claim 5: "a" should be changed to "the" before "starch derivative" in line 2.
- Claim 11: "the" should be inserted before "starch" in line 3; "esters" in line 2 and "derivatives" in line 3 should be changed to singular forms.
  - Claim 13: "is" in line 2 should be changed to "are" in agreement with the subject.
  - Claim 14: a dash should be used to replace "..." in lines 2 and 3.
- Claim 15: "a" should be changed to "the" before "non-solvent" and "solution," respectively. in line 2: "the" should be inserted before "starch" in line 2.
- Claim 18: "a" should be changed to "the" before "starch" and before "nonsolvent" in line 2
- Claim 20: "a" should be changed to "the" before "solution" in line 2 and before "non-solvent" in line 3: "the" should be inserted before "starch" in line 2.
- Claim 21: a dash should be used to replace "..." in lines 3 and 4; a comma should be placed after "mixture" in line 4; and the parentheses should be removed.

  Appropriate corrections are required.

Art Unit: 1793

### Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The claimed subject matter in question is aldehyde being used as the solvent according to claim 10.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- The claims are generally narrative and indefinite, failing to conform with current
   U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.
- 3. The independent claim 1 fails to clearly set forth the steps comprised in the process. For example, the first step should be rewritten as "forming a solution comprising..." The instant claim also contains confusing language in lines 5-8, which render the claim indefinite. For examination purposes, lines 5-8 are read "bringing the solution into contact with...which results in a dispersion, which comprises a precipitate..." in light of the suggested corrections to the objected limitations above.

Art Unit: 1793

7. Claim 3 recites the limitation "or, at the most, a quantity which is 20% by weight bigger than that," which renders the claim indefinite. For examination purposes, the instant claim is considered to end at "starch derivative" in line 2.

- 8. Claim 4 recites the limitations "a solution is formed which at least one of the following criteria can be applied to" and "the concentration of the solution is at least 1% by weight, preferably approximately 10-30% by weight." It is unclear to what substance the concentration is being referred. To correct the first limitation into proper English for examination purposes, it is read "...the solution that is formed meets at least one of the following criteria." The second limitation is considered to refer to the concentration of the starch derivative in the solution.
- 9. Claim 5 recites "or which does not break down at the said temperature." It is unclear what the phrase means, and which temperature is being referred to. The claim is narrative and indefinite. For examination purposes, the instant claim is read "...that the starch derivative has a glass transition point of at least 60°C, preferably at least 100°C."
- 10. Claim 7 recites the limitation "the starch ester" in line 1. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, claim 7 is considered to depend on claim 6 rather than 5. The instant claim also claims that starch ester is an ester formed of starch and C<sub>1-4</sub> alkane acid, preferably a starch acetate." However, it is unclear how a starch ester or acetate is derived from a starch and a C<sub>1-4</sub> alkane acid. For examination purposes, the instant claim is interpreted to mean that the starch ester is a starch acetate.

Art Unit: 1793

11. Claim 11 recites the limitation "the esters" in line 2. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the instant limitation is interpreted to mean "an ester."

- 12. Claim 12 recites "organic solvent residues" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is also unclear which organic solvent is being referred to and how the detection is conducted. For examination purposes, the instant claim is interpreted to mean that the precipitate separated from the liquid phase does not contain any residual solvent.
- 13. Claim 14 recites the limitation "the...solvent mixture" in line 4 and claim 21 "the solvent mixture" in lines 2-3 and 4, respectively. There is insufficient antecedent basis for these limitations in the claims. For examination purposes, the instant claim is interpreted to refer to just "the solvent."
- 14. Claim 16 is narrative and indefinite. For examination purposes, the claim is read "...characterized in that the pigment or filler product that is prepared comprises spherical pigments having an average particle size of approximately 90-1000 nanometers."
- 15. Regarding claim 17, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Similarly, "possible" in line 3 also renders the claim indefinite. Claim 17 also recites the limitations "water" and "the fine" in line 3. There is insufficient antecedent basis for these limitations in the claim. It is also unclear which "fine," which is being interpreted as "fine particles," is being referred to. For

Art Unit: 1793

examination purposes, "water" and "the fine" are interpreted as the non-solvent and any fine particles, respectively.

16. Claim 19 is narrative and indefinite. For examination purposes, the claim is read "...characterized in that the pigment or filler product that is prepared comprises a material having a particle size of approximately 1-100 micrometers and an average pore diameter of approximately 100-500 nanometers."

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1793

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

 Claims 1, 3, 4, 6, 8, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6.562,459 to Bengs et al.

Regarding claims 1, 6, and 9, Bengs et al. teach a method of manufacturing a starch-based material, comprising:

Forming a solution comprising a starch derivative, e.g. a starch ester, by dissolving the starch derivative in a suitable solvent, e.g. DMSO,

Bringing the solution into contact with a precipitant or a non-solvent in which the starch derivative does not dissolve, e.g. water, in order to precipitate the starch derivative from the solvent which results in a dispersion, which comprises a precipitate consisting of the starch derivative, and a liquid phase, comprising both the solvent and non-solvent, and

Removing the precipitate from the liquid phase comprising the solvent and nonsolvent (Claim 1; abstract; column 3, lines 6-24 and 38-42; column 5, lines 33-37; Example 1).

Bengs et al. do not expressly teach removing the solvent from the liquid phase and separating and recovering the precipitate from the non-solvent.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have separated the precipitate from the liquid phase in a batch manner or

Art Unit: 1793

continuously, because the court held the claimed continuous operation would have been obvious in light of the batch process of the prior art and so that the reverse must be true. See MPEP 2144.04. Also, changing the order of steps in a process does not impart patentability in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results). See MPEP § 2144.04. Furthermore, "the starch-based pigment or filler" is a recitation of an intended use of the claimed invention in the preamble. It must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP § 2111.02.

Regarding claim 3, Bengs et al. teach rapidly dissolving 1g of starch in 5ml of the solvent in Example 1b, which suggests that no excess solvent or just enough solvent is used to dissolve the starch derivative.

Regarding claim 4, Bengs et al. teach that the total concentration of the starch derivative in the solvent may vary within wide limits according to demand. It is preferably in a range from 0.02 g (starch derivative)/ml (solvent) to 1.0 g/ml, in particular from 0.05 g/ml to 0.8 g/ml and particularly preferably from 0.3 g/l to 0.6 g/l (column 5, lines 26-32). Bengs et al. teach adding 30 g of starch to 500 ml of solvent, which would be about 22 wt.% (Example 1).

Bengs et al. do not expressly teach that the concentration of the starch derivative in the solution is at least 1% by weight, preferably approximately 10-30% by weight.

Art Unit: 1793

However, it would have been obvious to one of ordinary skill in the art at time of invention to have varied the concentration of the starch derivative in the solution according to demand as suggested by Bengs et al. and optimized the concentration through routine experimentation. A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05fR-51.

Regarding claim 8, Bengs et al. teach that the starch can be chemically modified by esterification and/or etherification of a hydroxyl group (column 3, lines 38-42). That is, the starch ester can also be hydroxyl alkylated.

<u>Regarding claim 12</u>, Bengs et al. do not expressly teach that the precipitate separated from the liquid phase does not contain any residual solvent.

However, absent of such The absence of such a specific teaching would clearly suggest to one of ordinary skill in the art at time of invention that there were not any impurities such as residual solvent in the precipitate separated from the liquid phase. Furthermore, the skilled artisan would have not expected any residual solvent after extensive purification and drying as described in Example 1.

Regarding claim 13, Bengs et al. teach using DMSO as an example of the solvent and water as an example of the precipitant or non-solvent (Example 1); the solvent and the non-solvent are miscible.

Regarding claims 14 and 21, Bengs et al. teach that the solvent/ precipitant ratio is preferably selected within a range from 1:1000 to 1:4 (part of solvent/parts of

Art Unit: 1793

precipitant) preferably 1:100 to 1:10 and in particular 1:70 to 1:30 (column 5, lines 38-41). The ratio is usually based on mass.

Regarding claim 15, Bengs et al. teach introducing the solution into the precipitant to form spherical microparticles (abstract) and that the order in which solvent and precipitant are combined, for example whether the precipitant is added to the solvent or vice versa, is unimportant in this context. It is, however, important to ensure rapid mixing (column 5, lines 47-51).

Regarding claim 16, Bengs et al. teach that the particles may have average diameters (number average) of from 1 nm to 100 μm, preferably 100 nm to 10 μm and particularly preferably 1 μm to 5 μm (column 7, lines 38-41). A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claims 18 and 19, Bengs et al. teach that the starch derivative solution is added, while mixing, to the non-solvent (Example 1b).

Bens et al. do not expressly teach that a coral-like, porous pigment product having the claimed particle size and pore diameter is produced.

However, it would have been obvious to one of ordinary skill in the art at time of invention that the claimed coral-like, porous product was produced in the method provided by Bengs et al., because the skilled artisan would have expected the same

Art Unit: 1793

product from the same method, in light of the obvious modifications to the method of claim 1 as explained above and absent convincing evidence to the contrary.

<u>Regarding claim 20</u>, Bengs et al. teach that the starch solution is brought into contact with the non-solvent with stirring, i.e. in turbulent conditions (Example 1b).

 Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al. as applied to claim 1 above, in view of US 6,617,449 to Tanaka.

Regarding claim 5, Bengs et al. do not expressly teach that the starch derivative has a glass transition point of at least 60°C, preferably at least 100°C.

Tanaka, also relates to biodegradable starch esters made from esterified or acylated starch compounds, teach that the starch esters have a glass transition point by differential thermal analysis (JIS K 7121: referred to hereinafter as "glass transition point") of 140°C or less, preferably 130°C or less. The lower limit of the glass transition point shall be usually 80°C, preferably 100°C (column 2, lines 52-56).

It would have been obvious to one of ordinary skill in the art at time of invention to have recognized that the starch esters of Bengs et al. have the claimed glass transition point as evidenced by Tanaka, because a chemical compound and its properties are inseparable.

Regarding claim 7, Bengs et al. teach that the starch derivative can be chemically modified, for example, by esterification and/or etherification. "Measures for such modification are well known to the skilled worker." (column 3, lines 38-42).

Bengs et al. do not expressly teach that the starch ester is a starch acetate.

Application/Control Number.

Art Unit: 1793

Tanaka teaches that the starch ester can esterified or acylated by replacing hydrogens in reactive hydroxyl groups with, for example, C<sub>2-4</sub> short-chain acyl groups (abstract). A C<sub>2</sub> acyl group would give a starch acetate.

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have used a starch acetate as a starch derivative in the method of Bengs et al., motivated by the fact that Bengs et al. encourage the skilled artisan to use known methods of esterification, such as acylation demonstrated by Tanaka, to derive the desired starch ester for the method.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Bengs et al. as applied to claim 1 above, in view of Tanaka, further in view of US
 5.507.304 to Maheras et al.

Regarding claim 10, Bengs et al. do not expressly teach that solvent is a straightchain, branched or cyclic ketone or aldehyde.

However, it has been established for claim 7 that it would have been obvious to use a starch acetate such as that disclosed by Tanaka as the starch derivative in the method of Benos et al.

Maheras et al. relate to polymer blends composed of cellulose acetate and starch acetate and teach using ketones such as acetone to solubilize the polymer mixture (column 3, lines 21-26, 31-35, 37-39; and 53-67).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have used ketones suggested by Maheras et al. to dissolve starch acetate Art Unit: 1793

in the method provided by Bengs et al., motivated by the fact that Maheras et al. teach that starch acetate is soluble in appropriate solvents such as acetone and these solvents are volatile (column 3, lines 53-67) so that the removal of the solvent would be fast and efficient.

 Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al. as applied to claim 1 above, in view of US 4,011,392 to Rudolph et al.

Regarding claims 2 and 11, Bengs et al. do not expressly teach that a mixture of solvent and non-solvent is used as the solvent or that the degree of substitution of the ester groups of an ester functioning as the starch derivative is chosen in a way that the starch derivative is fundamentally insoluble in the non-solvent.

However, Rudolph et al., who also relate to starch esters, teach that the degree of substitution is a critical factor in determining the starch esters characteristics and performance particularly in coatings. In general, the hydrophobicity of the starch polymer increase substantially as the degree of substitution increases. This may be illustrated by the solubility properties of the starch polymer which changes from water-soluble, organic-insoluble at low degrees of substitution to water-insoluble, organic-soluble at high degrees of substitution (column 5, lines 11-19).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have appropriately chosen a degree of substitution for the starch esters so that the starch derivative is insoluble in the non-solvent, e.g. water, in the method

Art Unit: 1793

provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated that the starch derivative must be insoluble in the non-solvent in order for it to precipitate and insolubility in the non-solvent can be achieved by manipulating the degree of substitution of starch esters as suggested by Rudolph et al. The skilled artisan would also used a mixture of organic solvent, e.g. DMSO, and water as the solvent in cases when the degree of substitution requires a mixture of organic solvent and water for dissolving the starch ester in the method provided by Bengs et al.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Bengs et al. as applied to claim 15 above, in view of US 4,716,186 to Portnoy et al.

<u>Regarding claim 17</u>, Bengs et al. teach that the starch derivative is precipitated with water and separated and recovered (Example 1).

Bengs et al. do not expressly teach that the fine particles dispersed in the liquid phase are precipitated.

Portnoy et al. also relate to starch derivatives and teach that the starch derivative can be separated from impurities such as inorganic salts by for example, salting out (column 1, lines 51-63).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have further precipitated fine particles from the liquid phase after separating the starch derivative in the method provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated further extract the starch derivative from the liquid phase and possible getting rid of inorganic salts as suggested by Portnoy et al.

Art Unit: 1793

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 8:00 am EST to 5:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on (571)272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A. LORENGO/ Supervisory Patent Examiner, Art Unit 1793 /HENG M CHAN/ Examiner, Art Unit 1793